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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,907	07/10/2001	Richard T. Pon	213202.00260	7290

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EXAMINER

CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 02/10/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/720,907</b>	Applicant(s) <b>Pon et al.</b>	
	Examiner <b>L. E. Crane</b>	Group Art Unit <b>1623</b>	

**- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **--03--** MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

### Status

- ☒ Responsive to communication(s) filed on **01/0301 (IDS), 01/02/01 (amdt A), & 02/21/03 (amdt B)** -
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- ☒ Claims **---1-187---** are pending in the application. Claims **-[]-** have been cancelled.
- Of the above claim(s) **---[]---** is/are withdrawn from consideration.
- ☐ Claim(s) **---[]---** is/are allowed.
- ☒ Claims **---1-187---** are rejected.
- ☐ Claim(s) **---[]---** is/are objected to.
- ☐ Claim(s) **---[]---** are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on **-[]-** are ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on **-[]-** is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119(a)-(d)

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☒ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) **-[]-**.
- ☒ received in the national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: **-[]-**.

### Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). **--03--**
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other: **-[]-**

U.S. Patent Trademark Office

### Office Action Summary

PTO-326 (Rev. 06/19/01)  
S. N. 09/720,907

Paper No. **01252004**

Copy for ☒ FILE ☐ APPLICANT

Serial No. 09/720,907

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No claims have been cancelled, claims 6-7, 9-16, 21, 31-37, 39, 40-42, 44-49, 51, 58-62, 64-68, 70, 73, 79, 80-89, 91-94, 96-101, 103, 105, 111-121, 123, 126-130, 132-137, 139, 141, 149, 150-159, 164-168, 170-175, 177, 179, 182-184 and 187 and claims 18, 24, 63 and 161 have been amendeded, the disclosure has been amendmed in its text and by addition of one page (Seq. ID), and no new claims have been added as per the preliminary amendmdents filed January 2, 2001 and February 21, 2003. A Sequence Disclosure including an ECRF have been received, found accaptable and entered into the PTO sequence database. An Information Disclosure Statement (IDS) filed January 3, 2001 with copies of the cited references has been received and made of record.

Claims 1-187 remain in the case.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thompson*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. §§1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with the application. See 37 C.F.R. §1.78(d).

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Effective January 1, 1994, an registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

5 Claims 1-187 are rejected under the judicially created doctrine of obviousness-type double patenting and being unpatentable over claims 1-40 of U.S. Patent No. 6,015,895. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to effectively the same compounds and the same process of making said compounds suitable for application in a solid  
10 phase oligonucleotide synthesis.

Claims 1-187 are rejected under the judicially created doctrine of obviousness-type double patenting and being unpatentable over claims 1-40 of U.S. Patent No. 6,043,353. Although the conflicting claims are not identical, they are not patentably distinct from each other because  
15 they are directed to effectively the same compounds and the same process of making said compounds suitable for application in a solid phase oligonucleotide synthesis.

Claims 1-187 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in  
20 such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims have not met the written description standard of Regents of the University of California v. Eli Lilly (119F.3d 1559 at 1568;  
25 43 USPQ2d 1398 at 1406 (Fed. Cir. 1997)) which MPEP §2163 at page 2100-162, column 1, quotes as follows: "A definition by function alone 'does not suffice' to describe a coding sequence 'because it is only an

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indication of what the gene does, rather than what it is.” Applicant continues to rely on generic functional terminology in claim 1 including “linker moiety” and “organic radical” wherein the disclosure definition thereof does not overcome the functionality of the noted term. See also  
5 claims **53, 106, 144 and 185**. Subgeneric terms in claims **2-8** like “at least one carbon atom,” “C<sub>1</sub>-C<sub>300</sub> organic moiety,” “C<sub>1</sub>-C<sub>200</sub> organic moiety,” “C<sub>1</sub>-C<sub>100</sub> organic moiety,” “saturated organic moiety,” “unsaturated organic moiety,” and similar limitations found in claims **9-15 and 27-35** do not overcome this grounds of rejection. See also  
10 dependent claims **54-67 and other similarly structured claims**.

Claims **1-187** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use  
15 the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination  
20 of whether a conclusion of “undue experimentation” is appropriate are as follows:

A. The breadth of the claims which depend entirely on functional terminology (all independent claims) is excessive in light of the very limited number of examples in Table 2 of the disclosure.

25 B. The nature of the invention is directed to linker molecules with utility in solid support oligonucleotide synthesis.

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C. The state of the prior art is well developed as revealed by the substantial number of different linker molecules disclosed in the prior art of record.

5 D. The level of one or ordinary skill is moderate, the only requirement being mastery of the process of solid support derivatization and oligonucleotide synthesis.

E. The level of predictability in the art is fairly high because the organic chemistry being applied is well established and predictable.

10 F. The amount of direction provided by the inventor is limited to the examples provided in Table 2 and associated examples wherein a limited number of different solid support linkers are shown to be effective in oligonucleotide synthesis.

G. The existence of working examples is very limited as noted above.

15 H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive because of the immense and poorly defined scope of the claim language.

20 Claims 1-187 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

25 In claims 1, 53, 106, 144 and 185 the term "comprising" renders said claims indefinite because said term implies that the chemical structure of the compound being claimed contains additional structural component(s) not defined in the claim. Applicant is respectfully

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requested to substitute narrow language such as -- consisting of-- or the like for the noted term, and to include a much more detailed chemical formula for the generic class of substances intended to be claimed. Examiner suggests substitution of narrower language (-- consisting of --) for "comprising" at each occurrence. Similar substitutions would also be necessary in all dependent claims wherein any derivative of the term - to comprise" occurs.

In claims 1- the term "reusable" is superfluous without a limitations indicating what particular structural features render said substance "reusable" whereas other linkers are not reusable. See also claims 1-- 106, and all other claims wherein the noted term is found.

In claim 19, the term "R<sup>8</sup>" lacks antecedent basis in claim 18. Did applicant intend the term to read -- R<sup>a</sup> --? For the same error, see also claim 25, 71, 77, 124 and 162.

In claim 22 at line 7, the terms "C<sub>1</sub>-C<sub>40</sub> hydroxy group" and "C<sub>2</sub>-C<sub>40</sub> acrylate group" are internally contradictory and therefore technically impossible as presently formulated. "Hydroxy" is always " -OH " and contains no carbons and "acrylate" is " -O-C(=O)-CH=CH<sub>2</sub> " only. Also the term "C<sub>1</sub>-C<sub>40</sub> ester group" is incomplete for failure to specify the particular type of ester being included (carboxylate, sulfate, phosphate, etc. etc.). Appropriate clarification is respectfully requested. For the same errors, see also claims 15, 37, 67, 120,

In claim 22 at line 5, the term "selected from the group comprising" is technically incorrect because, unlike a properly formulated Markush group {selected from the group consisting of A, B, ... and X}, said term is open ended and thereby renders said claim lacking in properly defined metes and bounds. Examiner notes in claims 143 and 181 and

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similar lower numbered claims that applicant also mixes "or" and "and/or" terms into the Markush group; please pick "Markush" or "or" terminology because, as noted in the MPEP, they do not mix. See also claims 15, 21, 37, 42(lines 11, 20 and 23), 67, 73, 74, 94 (lines 11, 20 and 23), 120, 126, 130 (lines 11, 25, and 28), 142, 143, 158, 164, 168 (lines 11, 25 and 28), 180 and 181.

In claims 106-141, 144-179, 182-187 the disclosed process subject matter fails to include any reference to what chemical reagents are being used to catalyze or otherwise assist in the formation of new chemical bonds, thereby rendering the instant claims incomplete concerning the details to the step or steps required to make same. Even in the claims wherein reactants are listed, (claims 142-143 and 180-181) there is no direction as to whether one or multiple steps are required to execute the claimed processes.

Claim 142 is objected to because of the following informalities:

In claim 142 at line 1, the term "activating" is a misspelling of -- activating--.

Appropriate correction is required.

References made of record but not cited above are deemed to be either equivalents to the cited references or to be of interest as closely related prior art which shows the state of the relevant prior art.

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are (703) 308-4556 and 703-305-3592.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at (703)-308-4624.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

LECrane:lec  
**01/25/2004**



L. E. Crane, Ph.D., Esq.  
Patent Examiner  
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